

Application No. 10/658,078
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REMARKS/ARGUMENTS

Claims 1-14 remain in this application. Claims 10-12 have been withdrawn. Claims 4 and 5 have been amended.

Claims 1-9 and 13-14 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention. According to the Office action, the term "dissolution rate controlling polymer" is indefinite because there is no clear definition in the specification as to what constitutes a "dissolution rate controlling polymer". Furthermore, according to the Office action, "[a]ny polymer in the composition would be reasonably expected to affect the dissolution rate." Applicants respectfully submit that the term "dissolution rate controlling polymer" is a term of art known to those of ordinary skill in the art. Applicants submit that the indicated language when read in view of the specification is clear and will be understood by one of ordinary skill in the art. 35 U.S.C. §112, second paragraph, requires that the claims when read in light of the specification apprise those skilled in the art of the scope of the claim. See *Miles Labs., Inc., v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). Dissolution rate controlling polymers are well known to those of ordinary skill in the art as high viscosity polymers widely used in the matrix tablet formulations to control release of an active ingredient. In fact, Rampal et al. disclose various rate controlling polymers in the cited reference (WO 03/017981). As one of ordinary skill in the art would understand, not all polymers are considered dissolution rate controlling polymers. As such, one of ordinary skill in the art would not consider the polymers used as binders set forth in claim 5 to be "dissolution rate controlling polymers." Therefore, applicants respectfully submit that the term "dissolution rate controlling polymer" is not indefinite, but instead has a well established and commonly understood meaning known to the those of ordinary skill in the art. Accordingly, applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

Claim 4 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite because it is not clear whether the cited concentration range pertains to the filler or lactose. Claim 4 has been amended to clarify that the recited range refers to the pharmaceutically acceptable filler. Therefore, applicants request that the rejection be withdrawn.

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The Office action further indicates that claim 5 is indefinite because there is insufficient antecedent basis for the terms "said hydrophilic binder" and "a concentration of from about 1% to about 4%." Applicants respectfully submit that claim 5 satisfies 35 U.S.C. §112 with respect to antecedent basis for these terms. In the preliminary amendment filed July 13, 2005, claim 4 was amended to depend from claim 3. Claim 3 provides the necessary antecedent basis for "said hydrophilic binder." Applicants fail to see the objection to the recited concentration range of from about 1% to about 4% for the hydrophilic binder since the range for the amount of hydrophilic binder is not recited in any previous claim. Therefore, applicants fail to understand the Office's position that the range is not within the range of the parent claim. Therefore, applicants request that the rejection under 35 U.S.C. §112 be withdrawn.

The Office action further indicates that claim 5 is indefinite because it recites the limitation "in the dry form" and the claim is dependent from a claim referring to an aqueous solution of hydrophilic binder. Accordingly, claim 5 has been amended to delete the reference to the dry form. Therefore, it is respectfully requested that the rejection be withdrawn.

Claims 1-6, 8-9, and 13-14 stand rejected under 35 U.S.C. §102(e) as being anticipated by WO 03/017981 to Rampal et al. However, Rampal et al. fail to disclose or suggest the dosage form set forth in claims of the pending application. Rampal et al. clearly disclose the use of dissolution rate controlling polymers. The claims of the present application, by contrast, refer to a dosage form that does not contain a dissolution rate controlling polymer. Applicants submit that this is a limitation just as any other limitation and must be given weight in evaluating the patentability of the claims. Therefore, since Rampal et al. fail to disclose or suggest a dosage form that does not contain a dissolution rate controlling polymer, there can be no anticipation. Therefore, applicants respectfully request that the rejection under 35 U.S.C. §102 be withdrawn.


Claim 7 stands rejected as being obvious over Rampal et al. in view of WO 02/24174 to Vanderbist et al. However, Vanderbist et al. fail to remedy the shortcomings of the Rampal et al. reference and, therefore, claim 7 is non-obvious over the combination of the two cited references. Therefore, for these same reasons as set forth above, applicants respectfully submit that claim 7 is patentable over the cited references and request that the rejection be withdrawn.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance and favorable action on the merits is requested. Any questions

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concerning this application may be directed to applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,


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